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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,029	12/02/2003	Joan D. Leonard	12780/102	4719

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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/726,029	Applicant(s) LEONARD ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-46 and 48-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-46 and 48-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

FINAL ACTION

1. This action is responsive to Applicant's amendment and remarks filed December 18, 2006. Claims 21, 25, 50 and 53 have been amended. Claims 1-20 and 47 have been cancelled. Claims 21-46 and 48-61 are under examination. Applicant's declaration submitted by Dr. Leonard is acknowledged. The Declaration submitted Dr. Leonard and Applicant's remarks are sufficient to overcome the art rejections. However, Applicant's amendments to the claims necessitate new grounds of rejection.

Rejections Withdrawn

2. In view of Applicant's review and response the following rejections are withdrawn:
- a) rejection of claims 21-30, 50 and 52 under 35 U.S.C. 102(b), pages 2-5, paragraph 3.
 - b) rejection of claims 21-31, 50 and 52 under 35 U.S.C. 103(a), pages 5-8, paragraph 4.
 - c) rejection of claims 21-38, 42, 50 and 52 under 35 U.S.C. 103(a), pages 8-10, paragraph 5.
 - d) rejection of claims 21-38, 42-45 and 48-57 under 35 U.S.C. 103(a), pages 10-11, paragraph 6.
 - e) rejection of claims 21-39, 42-45 and 48-57 under 35 U.S.C. 103(a), pages 11-13, paragraph 7.
 - f) rejection of claims 21-45 and 48-57 under 35 U.S.C. 103(a), pages 13-15, paragraph 8.
 - g) rejection of claim 25 under 35 U.S.C. 112, second paragraph, page 15, paragraph 9.

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- h) rejection of claims 21-46 and 48-61 under 35 U.S.C. 112, second paragraph, page 15, paragraph 10.
- i) rejection of claims 21-46 and 48-61 under 35 U.S.C. 112, second paragraph, page 16, paragraph 11.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 3. Claims 21-46 and 48-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.* The amendment filed December 18, 2006 introduces new matter into the claims.

The claims have been amended to recite, "...such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering...". 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant's amendment introduces "new matter" that is not supported by the original disclosure.

The specification fails to show the claim limitation "a reduction in the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering". Applicant has failed to direct the Examiner as to where in the instant specification the support for this amendment is specifically shown or implied. In Applicant's response and marks (filed December 18, 2006) Applicant refers to incidence as a reduction in the number or percentage of cows showing clinical symptoms of mastitis after vaccination as compared to before vaccination. Applicant points to page 19, lines 17-31 of the specification to support this conclusion. The results on page 19 measure efficacy of the vaccine. There is no mention of symptoms of disease or the percentage of symptoms reduced. The Examiner has reviewed the instant specification and has failed to find the support for the amendment. Applicant is required to cancel the new matter in the reply to this Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-46 and 48-61 recite "whereby the incidence of mastitis in the bovine animals is reduced such that the number or percentage of bovine animals that show clinical symptoms of mastitis is less after such administering than before such administering..." "...". It is unclear as to what the Applicant is referring? What clinical symptoms are reduced? Does a reduction in clinical symptoms necessarily mean that incidence of mastitis is reduced? A symptom of a disease or disorder can be reduced

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and the subject still has the disease or disorder. The Clarification and/or correction is required.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Status of Claims

6. No claims are allowed.

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Conclusion

7. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 572-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
March 17, 2007


NITA MINNIFIELD
PRIMARY EXAMINER